

Remarks

The only ground of rejection pending in this application is under 35 USC 112, first paragraph, and relates to language added in applicant's prior response. Specifically, the issue is whether there is a written description in the specification that supports the phrase "wherein said tissue is other than an intervertebral disk" that was added to claim 1 to avoid a double patenting rejection.

The present rejection is traversed, as the specification clearly identifies restoration of intervertebral disk material as a subset of the generic "tissue" set of materials that can be restored, and the claims now simply claim the remainder of the original "tissue" set, namely all tissue except tissue associated with intervertebral disk repair. As recited at several locations of the Manual of Patent Examining Procedure, Eighth Edition, Revision 2, an inherent and implicit limitation of this type is sufficient to meet the written description requirements of 35 USC 112:

To comply with the written description requirement of 35 U.S.C. 112, para.1, ... each claim limitation must be expressly, implicitly or inherently supported in the originally filed disclosure. [MPEP 2163, A, 3, (b)]

While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.[MPEP 2163, I, A]
[Italics in original; underlining added for emphasis]

While applicant agrees that there is no *in haec verba* language and no express statement in the specification reading "wherein said tissue is other than an intervertebral disk," there is certainly an implicit and inherent indication: the method as applied to all physical tissues is disclosed, as is the specifically identified subset of methods used to repair intervertebral disk tissues. Thus, there is an adequate written disclosure of tissue "other than an intervertebral disk" when the specification as a whole is considered.

The original claims of the present application recited a "method for tissue augmentation or restoration in a mammal" without limitation as to the type of tissue being augmented or restored, and there was no objection to or rejection of those claims under 35 USC 112, first paragraph. That which is claimed now is a *part* of that which was originally claimed, and the part that was excluded ("intervertebral disk" repair) is a

specifically identified embodiment within the original disclosure. See, for example, paragraph [00043] on page 11, which reads as follows:

In another aspect, the present invention provides injectable bioelastic polymers and methods for their preparation and use, where the polymers are selected for and exhibit specific desired properties for tissue restoration in the area of intervertebral disc repair.

This immediately follows a general statement about the tissue restoration process that is not limited as to tissue type. Thus, the subject matter being now claimed is merely that part of the original claims other than the specific aspect that is set out in paragraph [00043], namely “tissue ... other than an intervertebral disk,” the language that is the basis of the examiner’s rejection at the present time.

Applicant understands that at least part of the basis of the rejection may be a belief by the examiner that the specification fails to “disclose *restoration* of all the tissues, *such as spinal cord tissues or tissues of specific organs within the body*” (Official Action, page 2, paragraph 3; emphasis added). Perhaps, however, this is simply the result of a difference in understanding of the meaning of the word “restoration” in the mind of the examiner and that of the applicant. From the applicant’s perspective, there is no intention to indicate that there is restoration of the function of tissues other than their *mechanical and physical* aspects (firmness, elasticity, strength, etc.). Some additional properties are described for preferred embodiments (e.g., the addition of materials to the polymers to attract cells or decrease scar formation), but nowhere in the specification is there an indication of any desire or intent to replace the *biological function* of the original tissue is being replaced; i.e., there is no restoration of the ability of a nerve to transmit a neural signal nor of an adrenal gland to secrete cortisol. However, there is a general discussion throughout the specification of how to make a polymer that has the proper *physical* properties for the material being replaced. See, for example, paragraph [00063] on page 20, which begins in the following manner:

As is apparent to one of ordinary skill in the art, the physical properties of the bioelastic polymer can be adjusted as described above, to exhibit desired characteristics, for example, viscosity, consistency, modulus of elasticity, stability, and the like. For example, the parent elastic protein-based polymer (GVGV_P)_n (SEQ ID NO:20), when prepared with n on the order of 200 and when cross-linked with 20 Mrads

of γ -irradiation (described below), forms an elastic matrix with an elastic modulus approximating that of natural vascular wall, in the range of 10^5 N/m². By variations in composition and conditions, the elastic modulus can be varied from 10^4 to 10^8 N/m². This provides the capacity to match compliance over the wide range of biological soft tissues.

Since the “restoration” being contemplated by the specification is in the field of plastic and reconstructive surgery and is of the *physical* aspects of replaced tissue and since there is specific disclosure of how to make a replacement implant with “the capacity to match compliance over the wide range of biological soft tissues” (see quoted paragraph immediately above and the following discussion in the specification), no limitation should be placed on the range of tissues being replaced, other than the limitation that the present claims are *not* directed to replacement of intervertebral tissue, as previously amended to avoid a double patenting issue.

If the examiner is still concerned with the “restoration” issue after consideration of the remarks set out above, he is invited and requested to examine new claim 76, which adds language to claim 1 to more clearly indicate that the “restoration” in question is a replacement of lost bulk in plastic surgery rather than restoration of non-mechanical function. Claim 76 recites a “method for tissue augmentation or restoration in a mammal *during a process of plastic or reconstructive surgery to replace missing tissue,*” while retaining (to avoid the double patenting issue of a prior Official Action) the language indicating that the “tissue is other than an intervertebral disk.” See page 1, paragraph [00003] of the specification for an example of support of this additional language, should the examiner find that this language may be helpful to some later readers of the claim. If requested, this language could be added to other claims, although applicant does not believe that such an amendment would be necessary.

Conclusion

In view of the remarks and amendments set out above, reconsideration and allowance of the present application is requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 843-5070.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, or 1.21 that may be required by this paper, to the extent not already covered by the enclosed extension of time, and to credit any overpayment, to Deposit Account No. 03-3117.

Dated: September 27, 2004

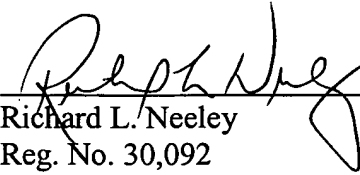
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